PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PC/4 -33316A	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2004/013419	International filing date *(day/month/year)* 25.11.2004	Priority date *(day/month/year)* 26.11.2003
International Patent Classification (IPC) or national classification and IPC A61K31/47, A61K9/28		
Applicant NOVARTIS AG		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☒	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23.08.2005	29.11.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Scarponi, U Telephone No. +31 70 340-

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/013419

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-28 as originally filed

   Claims, Numbers

   1-20 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/013419

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 19 in respect of industrial applicability

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 19

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/013419

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-20
	No:	Claims	1-9
Inventive step (IS)	Yes:	Claims	1-20
	No:	Claims	1-9
Industrial applicability (IA)	Yes:	Claims	1-18,20
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

Re Item III.

III.1. Present **claim 19** relates to subject-matter considered by this Authority to be covered by the provisions of **Rule 67.1(iv) PCT**. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of this claim **(Article 34(4)(a)(I) PCT).**

III.2. For the assessment of the present claim 19 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item V.

V.1. Reference is made to the following document:

D1 : WO 01/76573 A (NOVARTIS) 18 October 2001 (2001-10-18)
D2 : WO 2004/010980 A (NOVARTIS) 5 February 2004 (2004-02-05)
D3 : WO 2004/071403 A (LEK) 26 August 2004 (2004-08-26)
D4 : EP1514547 (KOWA CO. LTD.,JP) 16 March 2005 (2005-03-16)
& WO 03105848 (KOWA CO. LTD.,JP) 24 December 2003 (2003-12-24)

Unless otherwise indicated, reference is made to the relevant passages emphasized in the International Search Report.

V.2. **Document D1**, which is considered to represent the most relevant state of the art, discloses compositions for the same use as in the present Application and containing an HMG-CoA reductase inhibitor, notably pitavastatin (in association with other therapeutic agents). A specific example of a compressed core coated tablet containing fluvastatin is given, example conceivably applicable also to pitavastatin. From this, the subject-matter of independent claim 1 differs in that the disclosed pitavastatin-containing compositions (exemplified as tablets in the examples) should be made of a structured two-phase core coated by two different layers.
The subject-matter of claim 1 is therefore novel **(Article 33(2) PCT).**

V.3. The **problem** to be solved by the present invention (see the description, page 1, 2nd

paragraph) may be regarded as the preparation of pitavastatin-containing sustained-release compositions and tablets endowed with better pharmacokinetic properties.
The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step **(Article 33(3) PCT)** because - although being known coated compositions and tablets containing pitavastatin - none of the prior art documents suggests the preparation of pitavastatin-containing sustained-release compositions and tablets comprised of a structured two-phase core coated by two different layers in order to solve the problem posed by the present Application.

Re Item VI

Certain documents cited

Certain published documents

Although not being comprised in the relevant prior art for the purposes of **Art. 33 (2)** and **(3) PCT (Rules 64.1 and 64.3 PCT)**, the above mentioned **documents D2-D4**

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO 2004/010980	**5 February 2004**	**24.07.2003**	**25.07.2002**
WO 2004/071403	**26 August 2004**	**11.02.2004**	**12.02.2003**
EP1514547	**16 March 2005**	**16.06.2003**	**17.06.2002**
& WO 03105848	**24.12.2003**	**16.06.2003**	**17.06.2002**

are quoted according to **Rules 70.10** and **64.3 PCT** as they might become relevant in later regional phases, especially a European regional phase .